

**REMARKS**

Reconsideration of this application is requested. Claims 28 – 48 are active in the application subsequent to entry of this amendment.

The claims have been amended in order to more particularly point out and distinctly claim that which applicants regard as their invention, to replace non-statutory claims 15 and 16 with proper method of treatment claims and attend to the enablement rejections on pages 5-8 of the Official Action. More specifically, new claim 28 replaces claim 1, which contains an additional proviso to exclude the case where the substitution  $R_5$  of formula (III) is  $-\text{CO}-Z$  where  $Z=\text{OR}_7$  with  $R_7$  being a saturated or non-saturated, linear or branched  $\text{C}_1\text{-C}_4$  aliphatic hydrocarbon, according to the general definition of U.S. Patents 4,459,302 and 4,888,350. Claim 4 (now new claim 32) has been amended accordingly. In view of the above, claims 6, 10 and 11 (respectively referred to compounds (V), (XIV) and (XV)) have been cancelled.

Original claim 2 has been rewritten as two dependent claims 29 and 30 while claims 31-37 correspond to claims 3-5, 7-9 and 12, respectively. Claims 13, 14 and 18 have been withdrawn and "use of" claims and replaced with method of treatment claims 46-48. Methods of the therapeutic use of the disclosed and claimed compounds are discussed generally on page 14 of the specification. Claim 46 is directed to the methods specifically discussed and illustrated on pages 9-22, claim 47 to the method discussed and illustrated at pages 23-27 and claim 28 to the method illustrated on page 28 of the specification. New claims 38-45 correspond generally to previous claims 17 and 19-25, respectively. Synthesis claims 26 and 27 are withdrawn from consideration in order to reduce issues. It is submitted that the new claims presented above are compliant with 35 U.S.C. § 112, first and second paragraphs. Favorable consideration is requested.

Turning now to the art-based rejections, original claims 1-5, 17, 19, 21, 22, 25 and 26 have been rejected as allegedly being anticipated by published European application 80,053 and U.S. Patent No. 4,535,090. Original claims 1-17, 19-22, 25 and 26 stand

rejected as allegedly being "obvious" over the disclosures of these two documents taken in combination with three additional citations, one a French patent and two U.S. patents. These rejections are respectfully traversed for the following reasons:

The present invention provides nitrogen heterocyclic aromatic derivatives possessing a sustained duration of action (page 5, lines 23-25), endowed with high anti-gestative activity when administered as single-dose (page 5, lines 11-13). U.S. Patents 4,459,302 and 4,888,350 disclose some 120 different compounds altogether (pages 26 to 32) all referring to a chemical structure characterized by an ester moiety of the  $\text{CH}_2\text{-O-CO-R}_5$  type where  $\text{R}_5$  is an alkyl or similar substitution. U.S. Patents 4,459,302 and 4,888,350 do not give any indication of the fact that an ester type substituent would have been different from a carbonate type one, as the 98% of the described compounds are ester type compounds and no additional information is given for the carbonate type compounds.

Reading U.S. Patents 4,459,302 and 4,888,350, the skilled person simply would understand that both ester and carbonate type compounds are very similar, not just from the structural point of view but also from the biological and pharmacological perspective. Moreover, U.S. Patents 4,459,302 and 4,888,350 give no indication of the fact that only 4 of the 120 compounds which have been put all together in a long list, would have a sustained duration of action compared with the other 116 of the same list. Again, U.S. Patents 4,459,302 and 4,888,350 disclose the multi-dose treatment as the effective treatment in order to reach successful results, and while a single dose treatment is mentioned in passing, perhaps as an aside, it is never exemplified or explained.

The teaching of U.S. Patents 4,459,302 and 4,888,350 is that even if a single dose treatment could have been envisioned, the multi dose treatment was considered, developed and proved to be effective with the cited compounds. Among all the described compounds, there is no indication that the carbonate type compounds, that is the ones claimed in the present application, namely those having a long  $\text{C}_5\text{-C}_{20}$  alkyl chain, might have a different behavior compared to the ester type compounds.

In particular, there is no suggestion on how to solve the technical problem faced and solved in the present application. Actually, the technical problem solved by the present invention was not solved, nor faced, in U.S. Patents 4,459,302 and 4,888,350. In fact, the preferred compound according to the present invention (namely compound (VI) of now pending claim 7) not only has a sustained duration of action, **but is the most active compound, in comparison with carbonates (XV) and (XIV)**. See the evidence provided by applicant in his specification, page 21, table 2, column ED<sub>50</sub> μmoles/kg.

An Abstract has been supplied based on that contained in the underlying PCT application responsive to the examiner's comment on page 9 of the Action.

Replacement pages for pages 6-9, 15, 21, 24, 26, 27, 34, 42-45a, 52 and 53 are supplied from counsel's file copy. From my copy not all of these pages contain extraneous markings however the examiner's copy furnished by WIPO may be different. If for any reasons the pages furnished are unsatisfactory the examiner is requested to contact the undersigned for prompt resolution.

For the above reasons, it is respectfully submitted that the claims of this application define inventive subject matter. Reconsideration and allowance are solicited.

Respectfully submitted,

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